

[Doc. No. 45]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

ACTELION PHARMACEUTICALS LTD.
and ACTELION CLINICAL
RESEARCH, INC.,

Civil No. 12-5743(NLH/AMD)

Plaintiffs,

v.

APOTEX INC., et al.,

Defendants.

MEMORANDUM ORDER AND OPINION

This matter comes before the Court by way of Plaintiffs' Actelion Pharmaceuticals Ltd. and Actelion Clinical Research, Inc. (hereinafter, "Plaintiffs" or "Actelion") motion to stay discovery pending a resolution of a dispositive motion. (See Plaintiffs' Motion to Stay Discovery Pending Ruling on Dispositive Motion (hereinafter, "Pls.' Mot.") [Doc. No. 45].) For the reasons set forth herein, the Court grants Plaintiffs' Motion.

Plaintiff Actelion Pharmaceuticals Ltd. is a "pharmaceutical company" and Plaintiff Actelion Clinical Research, Inc. is an "affiliate" of Actelion Pharmaceuticals Ltd. (See Complaint for Declaratory Judgment [Doc. No. 1], 3.)

In this action, Plaintiffs seek a determination of whether Plaintiffs "have a legal duty to supply its patented pharmaceutical products" Tracleer and Zavesca "to potential rivals[.]" (See Memorandum of Law in Support of Plaintiffs' Motion to Stay Discovery Pending Ruling on Dispositive Motion (hereinafter, "Pls.' Br.") [Doc. No. 45-1], 1.) Defendants Apotex Inc. and Apotex Corp. (hereinafter, "Apotex"), Roxane Laboratories, Inc. (hereinafter, "Roxane"), Actavis Elizabeth LLC (hereinafter, "Actavis"), Johnson Matthey Inc. (hereinafter, "JM"), and Zydus Pharmaceuticals, Inc. and Cadila Healthcare Limited (hereinafter, "Zydus") (collectively, "Defendants") are generic drug manufacturers.¹ Each Defendant has sought to acquire samples of Tracleer, and Defendant Roxane has, in addition to Tracleer, sought samples of Zavesca. (See Defendants/Counterplaintiffs' Memorandum in Opposition to Plaintiffs/Counterdefendants' Motion to Stay Discovery at 2

¹ Plaintiffs' initial complaint named as Defendants only Apotex Inc., Apotex Corp., and Roxane Lab., Inc. By Order dated December 19, 2012, the Court granted Actavis' Motion to Intervene. (See Order [Doc. No. 39], Dec. 19, 2012.) By letter dated March 29, 2013, JM joined in Defendants' previously-submitted papers, and agreed "to be bound by the resulting decisions subject to any and all appeal rights." (See Letter [Doc. No. 66], 1.) By Order dated April 2, 2013, the Court granted JM's Motion to Intervene. (See Consent Order [Doc. No. 67], Apr. 2, 2013.) Thereafter, Zydus moved to intervene, joined in Defendants' previously-submitted papers, and agreed to "be bound by the decisions on the [m]otions subject to any and all appeal rights[.]" (See Text of Proposed Consent Order [Doc. No. 75-1], 1.) By Order dated July 9, 2013, the Court granted Zydus' motion. (See Consent Order [Doc. No. 78], 1, July 9, 2013.)

(hereinafter, "Defs.' Opp'n") [Doc. No. 49], 2.) Defendants allege that such samples are needed "to conduct bioequivalence studies of their generic versions[,] the results of which must be submitted to the United States Food and Drug Administration in order to obtain necessary approvals to market the generic versions. (See Defs.' Opp'n [Doc. No. 49], 2; see also Transcript of Proceeding Held on 3/12/2013 (hereinafter, "Transcript") [Doc. No. 71], 18.) There is no dispute that, despite Defendants' various requests, Plaintiffs have "refused" to provide Defendants with samples of these drugs. (See Pls.' Br. [Doc. No. 45-1], 1; see also Defs.' Opp'n [Doc. No. 49], 2.) Defendants assert that Plaintiffs' conduct in refusing to provide the samples purportedly prevented "approval of [Defendants'] generic products" and "thwart[ed] generic competition for these two products." (Defs.' Opp'n [Doc. No. 49], 2; see also Transcript [Doc. No. 71], 17.)

As set forth supra, Plaintiffs seek "a declaration that Actelion is under no duty or obligation to provide any quantity" of Tracleer or Zavesca to Defendants. (See Complaint for Declaratory Judgment [Doc. No. 1], 14; see also Pls.' Br. [Doc. No. 45-1], 3; see also Transcript [Doc. No. 71], 30.) Defendants each answered Plaintiffs' complaint, and asserted various affirmative defenses and counterclaims against

Plaintiffs.² On January 16, 2013, Plaintiffs moved for judgment on the pleadings under FED. R. CIV. P. 12(c) and to dismiss counterclaims under FED. R. CIV. P. 12(b)(6). (See Motion for Judgment on the Pleadings (hereinafter, the "dispositive motion") [Doc. No. 44].) At that time, Plaintiffs also filed the present motion to stay discovery. (See Pls.' Mot. [Doc. No. 45].) Thereafter, on March 12, 2013, the Court conducted oral argument on the motion to stay discovery, but reserved decision. (See Minute Entry [Doc. No. 62], 1.) At this time, the dispositive motion remains pending, with oral argument set for October 17, 2013. (See Text Order [Doc. No. 79].)

Plaintiffs contend that the circumstances warrant the issuance of a stay pending resolution of the dispositive motion because the motion "seeks a determination of the law based on undisputed facts" "requir[ing] no factual development." (Pls.' Br. [Doc. No. 45-1], 2-3.) Plaintiffs further contend that discovery prior to resolution of the motion would constitute "an unnecessary waste of resources" because a ruling regarding the

² Each Defendant independently alleges that Plaintiffs have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; violated the New Jersey Antitrust Act, N.J. STAT. ANN. § 56:9-3 and § 56:9-4; New Jersey's common law tortious interference; and seeks mandatory injunctive and declaratory relief. (See Apotex's Answer and Countercl. [Doc. No. 24], ¶¶ 60-109; Roxane's Answer and Countercl. [Doc. No. 25], ¶¶ 99-244; Actavis' Answer and Countercl. [Doc. No. 40], ¶¶ 43-92; JM's Answer and Countercl. [Doc. No. 69], ¶¶ 46-93.)

pending motion to dismiss may obviate the "need for discovery" or "narrow and streamline discovery." (Id. at 2-3.)

Defendants jointly contend that Plaintiffs' dispositive motion does not constitute good cause to stay discovery because Plaintiffs have not "demonstrate[d] a 'clear and unmistakable' likelihood of success on its potentially dispositive motion." (Defs.' Opp'n [Doc. No. 49], 6; see also Transcript [Doc. No. 71], 13-15.) Defendants further allege that Plaintiffs have "failed to demonstrate that the proposed discovery [would] be unduly burdensome or expensive[,] in light of Defendants' "very reasonable discovery plan." (Id. at 8.) Moreover, Defendants assert that a stay would prejudice Defendants' ability to: "(1) complete bioequivalence studies[;]" "(2) obtain FDA approval[;]" and "(3) bring [Defendants'] generic versions of Tracleer and Zavesca to market." (Id. at 9.)

Plaintiffs dispute that the standard for a stay requires a finding that there is a "clear and unmistakable" likelihood of success on the motion, but also assert that Plaintiffs' dispositive motion "rests on long-standing antitrust and patent law principles[,]" which present no factual issues. (Reply Memorandum of Law in Support of Plaintiffs' Motion to Stay Discovery Pending Ruling on Dispositive Motion at 5 (hereinafter, "Pls.' Reply") [Doc. No. 51], 3-5.) Moreover, Plaintiffs contend that even pursuant to Defendants' proposed

discovery plan, "[t]he burden, expense, and distraction to business that discovery ordinarily generates" may be entirely avoided if Plaintiffs' motion is granted. (*Id.* at 6; see also Transcript [Doc. No. 71], 10.) Plaintiffs dispute Defendants' assertion of prejudice because "Apotex first demanded samples of Tracleer in January 2011; Roxane demanded Tracleer in January 2012 and Zavesca as early as April 2010; and Actavis demanded samples of Tracleer in September 2011[,]" but no defendant sought relief from a court. (*Id.* at 5.) Plaintiffs argue that Defendants' assertion that a stay of discovery will further delay production of generic versions of Tracleer and Zavesca purportedly "rings hollow." (*Id.*)

Pursuant to Federal Rule of Civil Procedure 26(c), the Court may stay discovery only on a showing of "good cause" by the party requesting the stay. Gerald Chamales Corp. v. Oki Data Americas, Inc., 247 F.R.D. 453, 454 (D.N.J. Dec. 11, 2007) ("A protective order pursuant to FED. R. CIV. P. 26(c) may only be issued if 'good cause' is shown."); FED. R. CIV. P. 26(c)(1) (establishing that the court may issue a protective order with respect to discovery only for "good cause"); see also Perelman v. Perelman, No. 10-5622, 2011 WL 3330376, at *1 (E.D. Pa. Aug. 3, 2011) ("The burden is on the party seeking the stay [of discovery] to show 'good cause.'") (citations omitted).

"[M]atters of docket control and conduct of discovery are committed to the sound discretion of the district court."

In re Fine Paper Antitrust Litig., 685 F.2d 810, 818 (3d Cir. 1982); see also Coyle v. Hornell Brewing Co., No. 08-2797, 2009 WL 1652399, at *3 (D.N.J. June 9, 2009) ("In discovery disputes, the Magistrate Judge exercises broad discretion and is entitled to great deference.") (citations omitted); Chamales, 247 F.R.D. at 454 ("Magistrate Judges have broad discretion to manage their docket and to decide discovery issues, including whether to stay discovery pending a decision on a dispositive motion.") (citations omitted). However, "[m]otions to stay discovery are not favored because when discovery is delayed or prolonged it can create case management problems which impede the court's responsibility to expedite discovery and cause unnecessary litigation expenses and problems." Coyle, 2009 WL 1652399, at *3 (internal citations and quotation marks omitted).

In Landis v. N. Am. Co., 299 U.S. 248 (1936), the Supreme Court set forth the standard for a stay of proceedings and found that, the movant "must make out a clear case of hardship or inequity in being required to go forward, if there is even a fair possibility that the stay ... will work damage to [someone] else." Id. at 255. The power to stay proceedings "calls for the exercise of judgment, which must weigh competing interests" and "balance" the hardships with respect to the

movant and non-movant. *Id.* at 254-55; see Gold v. Johns-Manville Sales Corp., 723 F.2d 1068, 1076 (3d Cir. 1983) (balancing the potential hardship with respect to both parties). Thereafter, numerous courts further delineated the requisite showing with respect to "hardship or inequity[,]" see, e.g., Cima Labs, Inc. v. Actavis Group HF, Nos. 07-893, 06-1970, 06-1999, 2007 WL 1672229, at *8 (D.N.J. June 7, 2007), and further adapted the approach to reflect the additional considerations that arise where a stay is sought pending resolution of a dispositive motion. See Mann v. Brenner, 375 F. App'x 232, 239 (3d Cir. 2010) (recognizing that "[i]n certain circumstances it may be appropriate to stay discovery while evaluating a motion to dismiss where" resolution of the motion would render discovery futile).

Consequently, courts generally weigh a number of factors in determining whether to grant a stay including: "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party[,]" Cima Labs, 2007 WL 1672229, at *8 (citing Motson v. Franklin Covey Co., No. 03-1067, 2005 WL 3465664, at *1 (D.N.J. Dec. 16, 2005)); (2) whether denial of the stay would create "'a clear case of hardship or inequity'" for the moving party, Hertz Corp. v. The Gator Corp., 250 F. Supp. 2d 421, 424 (D.N.J. 2003) (quoting Gold, 723 F.2d at 1075-76); (3) "whether a stay would simplify

the issues and the trial of the case[,]” Cima Labs, 2007 WL 1672229, at *8 (citing Motson, 2005 WL 3465664, at *1); and (4) “whether discovery is complete and/or a trial date has been set.” Id. In assessing prejudice, the Court notes that, “the party seeking [a] protective order must show good cause by demonstrating a particular need for protection. Broad allegations of harm, unsubstantiated by specific examples or articulated reasoning” do not suffice. Cipollone v. Liggett Grp., Inc., 785 F.2d 1108, 1121 (3d Cir. 1986). Moreover, if a dispositive motion is pending, courts further consider whether the pending dispositive motion “appear[s] to have substantial grounds or, stated another way, do[es] not appear to be without foundation in law[,]” Victor v. Huber, No. 12-282, 2012 WL 2564841, at *2 (M.D. Pa. July 2, 2012) (internal quotations and citations omitted), in assessing “whether a stay would simplify the issues and the trial of the case[.]” Cima Labs, 2007 WL 1672229, at *8 (citing Motson, 2005 WL 3465664, at *1). However, it is well settled that “the mere filing of a dispositive motion does not constitute ‘good cause’ for the issuance of a discovery stay.” Gerald Chamales, 247 F.R.D. at 454 (internal citations omitted).

With respect to the first factor, the Court must consider whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party. See Cima

Labs, 2007 WL 1672229, at *8. In considering this factor, the Court notes that the hearing for Plaintiffs' dispositive motion has now been rescheduled for October 17, 2013. (See Text Order [Doc. No. 79], July 10, 2013.) At present, the Court finds that the delay in resolving the Plaintiffs' dispositive motion does not, without more, establish that undue prejudice will result from issuance of a stay. Defendants assert that staying discovery would offend the public's "'particularly great' interest in 'vigorously enforcing national anti-trust laws through the expeditious resolution of private antitrust litigation'" and would prohibit Defendants from performing studies necessary for FDA approval. (Defs.' Opp'n [Doc. No. 49], 9; see also Transcript [Doc. No. 71], 19.) However, the Court finds that this claim of prejudice is contradicted by Defendants' failure to file claims against Plaintiffs, despite the knowledge that Plaintiffs refused to provide samples of their products. See, infra.

With respect to the alleged hardship to Plaintiffs if a stay is denied, Plaintiffs generally contend that, "[t]he burden, expense, and distraction to business that discovery ordinarily generates (and which is commonly recognized) may be entirely avoided." (Pls.' Reply [Doc. No. 51], 6.) Defendants, however, assert that, "Actelion's failure to identify any specific prejudice that it would suffer from proceeding with

discovery is fatal to its request for a discovery stay." (Defs.' Sur-reply [Doc. No. 53], 7.) Defendants contend that their proposed phase discovery ameliorates any prejudice. (See Defendants.' Opp'n [Doc. No. 49], 8.) However, Defendants state that "phase one" would include interrogatories and document requests concerning "core documents[,]" and acknowledge that disputes would exist regarding "what those core documents are." (See Transcript [Doc. No. 71], 20.) Plaintiffs generally retort that the proposed discovery would be voluminous, "quite costly[,] and expensive." (Id. at 10.) Moreover, Plaintiffs contend that although "phase discovery sounds on its face like it can save expenses, in some instances it can actually be more burdensome because it requires duplicative searching." (Id. at 9.)

As Plaintiffs assert, "[d]iscovery, particularly in antitrust cases, can be extremely expensive." (Pls.' Br. [Doc. No. 45-1], 2 (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 558-59 (2007) (recognizing the unusually high cost of discovery in antitrust cases))). The Court concludes that the potential cost of discovery establishes a specific and substantiated risk of harm.³ See Cipollone, 785 F.2d at 1121 (requiring "specific

³ In Twombly, the Supreme Court acknowledged that "proceeding to antitrust discovery can be expensive." 550 U.S. at 558. Though Twombly, as noted by Defendants, involved a putative class action, the Court concludes that the nature of the proposed discovery in this case supports a stay, particularly in light of the number of parties and the parties' various representations

examples or articulated reasoning" to demonstrate "harm" or "a particular need for protection"). Therefore, the Court concludes that, on balance, the equities favor issuance of a stay.

With respect to the third factor, the Court must consider "whether a stay would simplify the issues and the trial of the case." Cima Labs, 2007 WL 1672229, at *8 (citing Motson, 2005 WL 3465664, at *1). In that regard, the movants bear the burden of establishing that issuance of a stay would simplify the issues for trial by "narrowing" or "outright eliminati[ng]" the need for discovery. Weisman v. Mediqa, Inc., No. 95-1831, 1995 WL 273678, at *2 (E.D. Pa. May 3, 1995) (generally noting that, "where a pending motion to dismiss" "may result in a narrowing or outright elimination of discovery[,]" "the balance [of competing interests] generally favors granting a motion to stay."). In this case, consideration of this factor further requires the Court to examine the impact of Plaintiffs' dispositive motion. In assessing such impact, the Court must first determine the appropriate standard under which to evaluate the dispositive motion. Defendants assert that the applicable standard requires the moving party "to demonstrate a 'clear and unmistakable' likelihood of success on its potentially

regarding the Defendants' proposed discovery plan. (See, e.g., Transcript [Doc. No. 71], 9-10, 19-20.)

dispositive motion."⁴ (Defs.' Opp'n [Doc. No. 49], 5-6.) Plaintiffs assert, however, that the Court need not engage in a substantive review of the dispositive motion in determining whether to issue a stay. (See Pls.' Reply [Doc. No. 51], 3-5.) Both parties further contend that Mann v. Brenner, 375 F. App'x 232 (3d Cir. 2010) endorses their respective articulations of the applicable standard. (Compare Transcript [Doc. No. 71], 32, with Transcript [Doc. No. 71], 33.)

The Court finds that the appropriate standard considers whether the pending dispositive motion "does not appear to be without foundation in law." See Victor, 2012 WL 2564841, at *2. If the dispositive motion is without foundation or otherwise frivolous, then the Court need not, in considering a stay request, engage in any inquiry regarding the filing impact of the dispositive motion. However, if there is no such showing, then the filing of a dispositive motion may favor the issuance of a stay where, as here, the Court finds that resolution of the dispositive motion may "narrow[]" or "outright eliminat[e]" the need for discovery. Weisman, 1995 WL 273678, at *2. A stay is provisional relief designed to maintain the status quo during the pendency of certain proceedings. See, e.g.,

⁴ Defendants contend that Gerald Chamales Corp. v. Oki Data Arms, Inc., 247 F.R.D 453, 454 (D.N.J. 2007), and Ariano Castro, M.D., P.A. v. Sanofi Pasteur Inc., No. 11-7178, Order [Doc. No. 102] (D.N.J. July 18, 2012), articulate such a standard.

Valansi v. Ashcroft, 278 F.3d 203, 207 (3d Cir. 2002) (noting the court's issuance of a stay pending the court's decision "[t]o preserve the status quo"). Any showing of a "clear and unmistakable" likelihood of success is, quite simply, antithetical to that purpose. Consequently, the Court rejects Defendants' argument that the applicable standard requires the moving party "to demonstrate a 'clear and unmistakable' likelihood of success on its potentially dispositive motion." (Defs.' Opp'n [Doc. No. 49], 5-6; see also Transcript [Doc. No. 71], 22.) Nor does the Court find that the Third Circuit case of Mann v. Brenner, 375 F. App'x 232 (3d Cir. 2010), requires such a showing.⁵ Although in Mann, the court noted that "none of Mann's claims entitle him to relief[,]" Mann, 375 F. App'x at 239, the Third Circuit did not delineate a standard that conditions stays upon an analysis of the merits of the underlying motion. Indeed, requiring this Court to opine on the underlying merits of the Plaintiffs' dispositive motion, in addition to the District Court's consideration, would be unduly duplicative. While clearly the mere filing of a dispositive motion does not, without more, constitute good cause for

⁵With respect to Castro, the Court notes that Castro relies upon Gerald Chamales. Castro, No. 11-7178, Order [Doc. No. 102], 2. The Court further notes that the rulings in Gerald Chamales and Castro were predicated upon the significant discovery that had already been commenced. Gerald Chamales, 247 F.R.D. at 456; Castro, No. 11-7178, Order [Doc. No. 102], n.2. Here, however, discovery remains in its preliminary stage.

issuance of a stay, this Court "need not 'form[] an opinion as to the merits' of the [pending dispositive] motion." See Perelman, 2011 WL 3330376, at *1 (E.D. Pa. Aug. 3, 2011) (quoting Weisman, 1995 WL 273678, at *2). Therefore, the Court examines whether the pending dispositive motion "does not appear to be without foundation[,]" Victor, 2012 WL 2564841, at *2, or otherwise frivolous.

Here, there is no contention that Plaintiffs' dispositive motion is without basis, frivolous, or filed solely for a dilatory purpose. Plaintiffs contend that the "dispositive motion rests on long-standing antitrust and patent law principles that respect the fundamental right of a firm like Actelion to deal—and refuse to deal—with whomever it chooses[.]" (Pls.' Reply [Doc. No. 51], 4.) Defendants have not filed an application with the Court seeking sanctions under Federal Rule of Civil Procedure 11 with respect to Plaintiffs' filing of the dispositive motion. Rather, Defendants dispute the dispositive motion on substantive grounds. (See Defs.' Opp'n [Doc. No. 49], 6; see also Defs.' Sur-reply [Doc. No. 53], 4.) Thus, it does not appear that Plaintiffs' dispositive motion is without foundation in law or otherwise frivolous. Therefore, the Court concludes that the filing of the motion may be considered, and examines how the motion's resolution may impact the overall adjudication of this action. In certain circumstances, the

nature of the dispositive motion may be such that any resultant resolution may have little impact on the ultimate scope of discovery. Thus, this factor requires an individual determination in light of the specific circumstances of a given case. Here, Plaintiffs contend that, "[i]f the Court grants Actelion's Motion for Judgment on the Pleadings and to Dismiss Counterclaims, then there will be no need for discovery." (Pls.' Br. [Doc. No. 45-1], 3; see also Transcript [Doc. No. 71], 29.) Defendants Apotex, Zydus, and JM concede that a resolution of the dispositive motion favorable to Plaintiffs would obviate the need for discovery. (See Transcript [Doc. No. 71], 23.) Only two Defendants, Roxane and Actavis, dispute Plaintiffs' assertion. (See Transcript [Doc. No. 71], 37, 40.) In light of Plaintiffs' assertion that a favorable resolution of Plaintiffs' dispositive motion would end this litigation, and certain Defendants' agreement with respect to such effect, the Court concludes that "a stay would simplify the issues and trial of the case[,]" Cima Labs, 2007 WL 1672229, at *8 (citing Motson, 2005 WL 3465664, at *1), and accordingly, that this factor, on balance, favors entry of a stay.

With respect to whether discovery is complete and whether a trial date has been set, the Court notes that the case remains in its initial stages and no trial date has been set. Moreover, Plaintiffs' complaint was filed on September 14, 2012

(see Complaint for Declaratory Judgment [Doc. No. 1]), with the present motion filed shortly thereafter on January 16, 2013. Such temporal proximity supports the issuance of a stay because no party has engaged in significant production or protracted motion practice. Therefore, the Court finds this factor likewise favors entry of a stay.

Consequently, the Court concludes that the factors as set forth herein warrant a stay of discovery. Therefore, for the reasons set forth above,

IT IS on this 6th day of September 2013,

ORDERED that Plaintiffs' Motion to Stay Discovery [Doc. No. 45] shall be, and is hereby, GRANTED.

s/ Ann Marie Donio _____
ANN MARIE DONIO
UNITED STATES MAGISTRATE JUDGE

cc: Hon. Noel L. Hillman